REMARKS

This is in response to the Official Action mailed Ocotber 23, 2002 for the above-captioned application. Applicants request an extension of time sufficient to make this paper timely, and enclose the fee. The Commissioner is authorized to charge any additional fees or credit any overpayments to Deposit Account No. 15-0610.

Claims 1-40 are pending in this application. Claims 39 and 40 have been amended to be dependent on claim 38, rather than claim 1.

The Examiner has rejected claims 1-22 and 38-40 for obviousness type double patenting in view of US Patent No. 6,051,428. Applicants will file a terminal disclaimer if such is appropriate upon consideration of claims found to be allowable over the art in this case.

In response to the rejection under 35 USC § 112, second paragraph, Applicants have amended claims 1-40 to replace the term "immunomodultary" with "immunostimulatory" as suggested by the Examiner. It bears note, however, that the term which the Examiner asserts is indefinite is used in the claims of the issued Boursnell patent.

The Examiner also rejected claims 1-22 and 36-40 under 35 USC § 112, second paragraph. The Examiner states that the goal of the method is to produce tumor cells useful as vaccines, and it is suggested by the Examiner that this is inconsistent with limitation in dependent claims that the transduction can be performed *in vivo*. Applicants respectfully disagree. The method of the invention result in the formation of an autologous vaccine against tumor cells of an individual. This can be accomplished by removing tumor cells and transducing them and reintroducing them, or by achieving the transduction *in vivo*. There is no inconsistency, and hence no ambiguity. Furthermore, Applicants disagree with the assertion that claim 36, which is directed to transduced tumor cells wherever they may be found, reads on a human. The claims are directed to transduced cells, whether they are transduced *ex vivo* and reintroduced, or transduced *in vivo*. The claims are not directed to a human organism. The fact that cells may be present in a human does not make the subject matter improper, anymore than the fact that a drug may be formed *in vivo* from a precursor renders that unpatentable.

The Examiner states that claims 4-6 are indefinite because claim 4 omits an essential step. Applicants have amend claim 4 to recite a step of "administering transduced tumor cells" which is generic for either the *ex vivo* or the *in vivo* approach.

The Examiner rejected claims 1-3 and 7-40 under 35 USC § 102(e) as obvious over US Patent No. 6,344,445 of Boursnell. Without conceding that Boursnell is prior art, Applicants point out that it appears the sole basis for the assertion of anticipation is the statement bridging columns 7 and 8, that "where nucleotide sequences encoding more than one immunomodulating protein are inserted,m they may comprises more than one cytokine or may be a combination of cytokine(s) and accessory molecules." Applicants respectfully submit that this statement, unsupported by any examples or specific enabling disclosure, and unsupported by any evidence that the patentee, Boursnell, was actually in possession of such an invention (as required for the written description requirement of § 112) means that this reference may not be relied upon as an anticipatory disclosure. Otherwise, mere speculation, unsupported by the research effort necessary to obtain a patent in a biotechnology field would render such a patent unavailable. Standards for patentability and anticipation must be congruent. In the case of the Boursnell patent, there is no data showing any actual tumor reduction activity, or demonstrating the ability of even a single species of cytokine in a HSV vector to serve in a vaccine capacity. Thus, amy assertion of utility in this area are merely speculation, unsupported by a disclosure that meets the requirements of 35 USC § 112, first paragraph. Thus, the rejection should be withdrawn.

The Examiner states that preamble language cannot serve to limit the scope of the claims where it merely states an intended use, and where the body of the claim does not depend on the preamble for completeness. Both cases which the Examiner cites however, relate to product claims (an article and a product-by-process), and the MPEP section cited refers to "apparatus, article and composition claims." The bulk of the claims at issue here, however, are method claims. The Examiner has not explained how the goal of a recited method can ever be deemed surplus such that it may fairly be ignored.

Finally, Applicants would further point out that the Examiner has failed to establish anticipation with respect to a number of the dependent claims rejected. For example, the

reference contains no specific disclosure of a combination of IL-2 and IL-12 as recited in claim 19 and 35, or of a combination of a cytokine and a costimulatory factor as recited in claims 20, 21, 32 and 33. Thus, there is plainly no disclosure of this specific invention, making a rejection under § 102 improper.

Reconsideration of the application in view of the remarks herein is respectfully requested.

Respectfully submitted,

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